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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,588	10/20/2003	Takahiko Ishiguro	Q78097	3813
23373	7590	11/01/2005	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			WHISENANT, ETHAN C	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/687,588	<b>Applicant(s)</b> ISHIGURO ET AL.	
	<b>Examiner</b> Ethan Whisenant, Ph.D.	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 OCT 03, 12 DEC 03, and 06 FEB 04.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/345,761.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**NON-FINAL ACTION**

1. The applicant's Preliminary Amendments filed 20 OCT 03, 12 DEC 03, and 06 FEB 04 has been entered. Following the entry of the Preliminary Amendments, **Claim(s) 29-46** is/are pending.

**SEQUENCE RULES**

2. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

**35 USC § 112- 2nd Paragraph**

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**CLAIM REJECTIONS under 35 USC § 112- 2ND PARAGRAPH**

4. **Claim(s) 29-46** is/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claim 29** is indefinite because there is no nexus between the preamble and the claim steps. Claim 29 in its preamble direct to a method which is to accomplish a particular goal. However, none of the claim steps states that this goal is accomplished. For clarity, claimed methods should recite that the purpose of the method has been attained (i.e. provide a nexus between the preamble and the claim steps).

### REASON FOR ALLOWANCE

5. The examiner has carefully considered the obviousness rejection of the claimed invention made in the parent application (USSN 09/345,761) over Davey et al. [US 5,409,818(1995)] in view of Olsen et al. [WO 91/04340 (1991)]. This examiner finds said rejection to be untenable and accordingly finds Claims 29-46 to be allowable over the prior art of record.

This examiner finds that Claim 29 is allowable over the prior art of record because the prior art considered does not teach or reasonably suggest the method for assaying for a specific nucleic acid sequence that is within a target RNA as recited in Claim 29. In particular, the closest prior art Davey et al. [US 5,409,818(1995)] do not teach or reasonably suggest, either alone or in combination with the other prior art considered {e.g. Olsen et al. [WO 91/04340 (1991)]}, the method for assaying for a specific nucleic acid sequence that is within a target RNA as recited in Claim 29 wherein said target RNA is hybridized to a reagent (A), which is a single-stranded oligo nucleic acid complementary to a sequence 5' of, and adjacent to, the 5' end of said specific nucleic acid sequence that is within the target RNA, which allows the target RNA to be cut at the 5' end of the specific nucleic acid sequence by the action of a reagent (D), which is a ribonuclease that degrades RNA in a DNA-RNA double-strand; and cutting the target RNA at the 5' end of the specific nucleic acid sequence with reagent D to give a product'. Most importantly to the obviousness rejection of the claimed invention made in the parent application (USSN 09/345,761) over Davey et al. [US 5,409,818(1995)] in view of Olsen et al. [WO 91/04340 (1991)], the examiner finds that Olsen et al. does not teach preparing the target RNA as is required by the claimed invention and as recited above.

### CONCLUSION

6. **Claim(s) 29-46** is/are rejected and/or objected to for the reason(s) set forth above.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (571) 272-0754. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (571) 272-0745.

The Central Fax number for the USPTO is (571) 273-8300. Before faxing any papers, please

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inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).



**ETHAN WHISENANT**  
**PRIMARY EXAMINER**  
Art Unit 1634

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### Search Notes

**31 OCT 05**

**Databases searched: USPATFULL, USPG-PUBS and EUROPATFULL via EAST, CAlus, Medline**

Reviewed the parent(s), if any, and any search(es) performed therein : see the BIB data sheet

Reviewed, the search(es), if any, performed by prior examiners

Search terms:

Inventor(s) : e.g. Ishiguro T?/au

Target RNA

Reverse transcriptase or RT or RNA dependent DNA polymerase

Promoter

Enhancer

DNA dependent RNA polymerase

RNase H or RNaseH